formally evaluate the validity of the screens with regards to their ability to correctly identify ADEs. Validity was expressed as positive predictive value (PPV).
RESULTS: Ten studies published between 1992 and 2000 met the inclusion criteria. Three approaches used to measure ADE incidence were identified. Two studies screened for generic adverse outcomes (e.g., inpatient deaths), the average PPVs were 1% and 17.4%. Five studies exclusively screened for surrogate outcomes (antidotes commonly used to treat ADEs, or critical lab values, such as elevated creatinine or drug levels) to predict the occurrence of an ADE, with PPVs of 9, 12, 13, 18 and 37%. Three studies tested screens that combined medications and intermediate outcomes (PPVs 12.4, 45 and 53%).
CONCLUSIONS: Automated health care data screens show promise as ADE incidence measure. Their current validity, however, does not appear to be sufficient for cross-sectional comparisons or the evaluation of quality improvement initiatives. Increasing sophistication of the screens by including multiple variables that link process components (e.g. medication) along with adverse outcomes or surrogates (e.g. lab values, antidotes) appear to increase screen validity.

MENTAL HEALTH (including Alzheimer's Disease, Dementia, Alcoholism, and Attention Deficit Disorder)—*Clinical Outcomes Presentations*

PMH1

USEFULNESS OF ELECTRONIC COMPLIANCE DATA IN AN EFFECTIVENESS TRIAL

Cramer J[1], Rosenheck R[1], Krystal J[1], Kirk G[2], Krol W[2]
[1]Yale University School of Medicine, West Haven, CT, USA; [2]Dept. of Veterans Affairs, Perry Point, MD, USA

OBJECTIVE: Effectiveness trials are designed to evaluate patients in their natural setting with fewer constraints than in efficacy trials. The less-structured environment can result in a failed trial if participant activity is unknown. We prepared for this possibility by including electronic monitoring of medication dosing in a multicenter trial.
METHODS: The trial was designed to assess the effectiveness of naltrexone for the treatment of chronic alcoholism. Patients took either naltrexone or placebo once daily, using MEMS caps (APREX, Union City, CA) on their medication bottles to record the date and time of each opening. We planned analyses by intention-to-treat and covarying compliance as continuous and categorical variables (grouped as taking medication during 0–24%, 25–49%, 50–74%, >75% of weeks).
RESULTS: Primary endpoints showed no differences between treatment groups at 3 months. Electronic monitoring revealed that patients took 72 + 31% of naltrexone and 70 + 31% of placebo doses (overall compliance rates). Naltrexone was taken by 13%, 11%, 12%, and 65% of patients by category. Placebo was taken by 14%, 14%, 11%, and 61% of patients by category. Compliance rates were not significantly different overall or by category between treatment groups. Planned secondary analyses demonstrated that compliance was a predictor of success ($p = 0.03$ for drinks/day), with no interaction for treatment.
CONCLUSION: These data demonstrate the value of electronic compliance measurement that provided data on any period needed for analyses. Without these data, the results of a complex and expensive study would have been questioned. Critics could have charged that compliance rates differed among treatment groups, or that inadequate amounts of medication were taken to assess outcomes.

PMH2

ESTABLISHING THE EXPECTED RATE OF COGNITIVE DECLINE IN ALZHEIMER'S DISEASE

Caro JJ[1], Ward A[1], Kelley H[1], Ishak K[2], Raggio G[1], Robinson K[3], Molloy W[4]
[1]Caro Research Institute, Concord, MA, USA; [2]Caro Research Institute, Dorval, QC, Canada; [3]Janssen-Ortho Inc, Toronto, ON, Canada; [4]McMaster University, Hamilton, ON, Canada

The prognosis for patients with Alzheimer's disease is important information for physicians to be able to provide patients and their relatives as an aid to making appropriate arrangements before the severe stage is reached.
OBJECTIVES: To provide prognosis aids for patients with mild or moderate Alzheimer's disease based on the standardised Mini-Mental State Examination (SMMSE).
METHODS: Data from a Canadian cohort study of 206 patients with an initial SMMSE between 10 and 24 were used to find determinants of the three year probability of reaching a highly dependent stage, defined as SMMSE <10. The regression equations were also used to derive a reference failure-time curve. The predicted progression was compared with that observed in a US study (N = 597).
RESULTS: Proportional hazards analyses showed that at the mild stage (SMMSE 19 to 24) the presence of hallucinations was associated with a more rapid decline, whereas at the moderate stage (SMMSE 10 to 18) the important predictors of decline were a lower baseline SMMSE score and longer time since onset. Absence of hallucinations in patients with an SMMSE above 18, implied a 79% probability of remaining independent after three years; presence of hallucinations reduced this to 52%, while a prior rate of decline of 2 points/year did so even further to 43%. Less than half of patients whose SMMSE was already below 19 and who had symptoms for five years or longer remained independent after three years. An initial score below 14 resulted in a probability below 30%. The predictions based on the Canadian study showed reasonable agreement with the progression observed in the US study.
CONCLUSIONS: These equations permit estimation of the expected progression of Alzheimer's disease, and will